AUG 19 2011

Section III - 510(k) Summary of Safety and Effectiveness

K103027

sybron dental specialties

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Claudia Ortiz - Contact Person
Phone number: 714.516.7981
Fax number: 714.516.7488

Date Summary Prepared: May 31, 2011

Device Name:

- Trade Name - ***ELECTROtorque TLC 4893 with INTRAmatic KL 702***
- Common Name - Dental Handpieces and Accessories
- Classification Name - Dental Handpieces and Accessories, per 21 CFR § 872.4200

Devices for Which Substantial Equivalence is Claimed:

- Bien Air, *Optima MX (K042759)*
- Sirona Dental Systems GmbH, *Sirotorque L (K031584)*
- Kaltenbach & Voigt GmbH, *COMFORTtronic 4894 (K080677)*

Device Description:

The *ELECTROtorque TLC 4893* dental control unit is a stand-alone system for operating electrically-driven KaVo handpieces. External power supply provides electric power to the unit. The 4-hole tubing connected to the unit supplies chip /cooling air, water and pressure signal. The speed of the electric handpiece is controlled by air pressure. The control unit is positioned close a treatment unit at the location preferred by the dentist. The *ELECTROtorque TLC 4893* system consists of a base unit with a motor hose, an electrical motor, a transformer, and a power cord. The *ELECTROtorque TLC 4893* dental control unit is a software-driven device. The software controls the following features: (1) Motor control, (2) Motor start / stop behavior, (3) Motor speed, (4) Motor performance, (5) Measuring power consumption, (6) Monitoring power consumption, and (7) *SAFEdrive*. The new *SAFEdrive* software feature monitors the power consumption of electrical hand pieces to reduce the probability or severity of overheating, thus minimizing the risk of burns to the patient. The user can navigate through the software menu via the control panel (see Figure 2.0).

The *INTRAmatic KL 702* motor is an electrical low-voltage motor for dental purposes according to ISO 11498 type 2. The motor connects onto the KaVo specific tubing of the dental treatment unit ELECTROtorque. The speed of the *INTRAmatic KL 702* is controlled by air pressure of the dental treatment center. The converted pneumatic output signal (electrical energy) from a dental treatment center drives the motor to operate an electrically-driven dental handpiece. Electrically-driven dental handpiece, which conform to ISO 3964, can be attached on the motor. The *INTRAmatic KL 702* is intended only for dental treatment by a dental professional.

Intended Use of the Device:

The *ELECTROtorque TLC 4893* is intended to convert pneumatic output from a dental treatment center to electrical energy to drive the *INTRAmatic KL 702* motor for operation of electrically-driven dental handpieces. These devices are designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The *ELECTROtorque TLC 4893* dental control unit is substantially equivalent to other legally marketed devices in the United States. The *ELECTROtorque TLC 4893* functions in a manner similar to and is intended for the same use as the COMFORTtronic 4894 marketed by Kaltenbach & Voigt, the Optima MX marketed by Bien Air, and to the Sirotorque L marketed by Sirona Dental Systems.
The *ELECTROtorque TLC 4893* is similar to all three predicate devices in that it is a software-driven dental control unit consisting of a base unit with a motor hose, an electrical motor, a transformer, and a power cord. As the other three predicate devices, it is integrated in a dental treatment center and it uses the same water system and the same power supply. The software in the *ELECTROtorque TLC 4893* device as well as the software of the three predicate devices control the following features: (1) Motor control, (2) Motor start / stop behavior, (3) Motor speed, (4) Motor performance, (5) Measuring power consumption, and (6) Monitoring power consumption. The *ELECTROtorque TLC 4893* differs from all three predicate devices in that the *ELECTROtorque TLC 4893* software has an added software function called *SAFEdrive*. This *SAFEdrive* function monitors the power consumption to reduce the probability or severity of overheating of electrical handpieces, thus minimizing the risk of burns to the patient.

The *INTRAmatic KL 702* motor is substantially equivalent to other legally marketed devices in the United States. The *INTRAmatic KL 702* functions in a manner similar to and is intended for the same use as the COMFORTdrive 200XDA marketed by Kaltenbach & Voigt, the Mikromotor MX marketed by Bien Air, and to the motor BL ISO marketed by Sirona Dental Systems. The *INTRAmatic KL 702* is similar to all three predicate devices in that it is an electrical low-voltage motor for dental purposes according to ISO 11498 type 2. The *INTRAmatic KL 702* differs only from the COMFORTdrive 200 XDA in that it can also rotated counterclockwise and it can be used with any electrically-driven dental handpiece that has a handpiece connection that conforms to ISO 3964.

Non-Clinical Test Data:

Temperature and energy studies have been conducted to determine the parameters for the new *SAFEdrive* software function. The *ELECTROtorque TLC 4893* software has been successfully validated to confirm the performance of the device. The software validation included testing of

the new *SAFEdrive* software function to demonstrate that with this added function, the *ELECTROtorque TLC 4893* is capable of detecting defective electrical handpieces to reduce the probability or severity of overheating, thus minimizing the risk of burns to the patient. Testing of electromagnetic compatibility and electrical safety has been conducted in accordance with applicable recognized consensus standards. Also sterilization and biocompatibility studies were done to determine the safety and effectiveness of the *INTRAmatic KL 702*.

Clinical Test Data:

Clinical testing has not been conducted on these products.

Conclusion:

Based upon similar technological / performance characteristics as compared to the predicate devices, and successful validation of the *ELECTROtorque TLC 4893* software, the clinical performance of the *ELECTROtorque TLC 4893 and INTRAmatic KL 702* is deemed to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kaltenbach & Voight GmbH
C/O Ms. Claudia Ortiz
Compliance Director, Regulatory Affairs & Quality Assurance
Sybron Dental Specialties, Incorporated
1717 West Collins
Orange, California 92687

AUG 19 2011

Re: K103027
Trade/Device Name: ELECTROtorque TLC 4893 with INTRAmatic KL 702
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW, EKX
Dated: July 22, 2011
Received: July 25, 2011

Dear Ms.Ortiz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I - Indications for Use

510(k) Number (if known): K103027

Device Name: *ELECTROtorque TLC 4893 with INTRAmatic KL 702*

Indications for Use:

The *ELECTROtorque TLC 4893* is intended to convert pneumatic output from a dental treatment center to electrical energy to drive the *INTRAmatic KL 702* motor for operation of electrically-driven dental handpieces. These devices are designed for use by a trained professional in the field of general dentistry.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103027

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)